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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10260, CMS-10305 and CMS-10622]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10260 Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3)

CMS-10305 Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g))

CMS-10622 Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Advantage and Prescription Drug Program: Final Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3); Use: We require that Medicare Advantage (MA) organizations and Part D sponsors use standardized documents to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Social Security Act (Act) and 42 CFR 422.111(b) for MA organizations, and section 1860D-1(c) of the Act and 42 CFR 423.128(a)(3) for Part D sponsors. The regulatory provisions require that MA organizations and Part D sponsors disclose plan information, including: service area, benefits, access, grievance and appeals

procedures, and quality improvement and quality assurance requirements by September 30th of each year. The MA organizations and Part D sponsors use the information to comply with the disclosure requirements. We will use the approved standardized documents to ensure that correct information is disclosed to current and potential enrollees.

For 2017, CMS has a total of nine standardized ANOC/EOC documents: Health Maintenance Organization, Cost, Dual Eligible Special Needs, Medicare Medical Savings Account, Private-Fee-For-Service, Preferred Provider Organizations, Preferred Provider Organization with Prescription Drugs, Health Maintenance Organization with Prescription Drug, and Prescription Drug. These standardized documents will be used by MA organizations and Part D sponsors for the 2018 contract year.

In revising the standardized ANOC/EOCs for contract year 2018, we did not add to or remove any section from the prior contract year ANOC/EOC models. MA organizations and Part D sponsors are still required to use the standardized language in the ANOC/EOC models and to send this document to current members at least 15 days prior to the start of the annual enrollment period or by September 30, 2017 for the 2018 enrollment season, based on 42 CFR 422.111(a) (3) and 423.128(a)(3). Form Number: CMS-10260 (OMB control number: 0938-1051); Frequency: Yearly; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 805; Total Annual Responses: 805; Total Annual Hours: 9,660. (For policy questions regarding this collection contact Gladys Valentin at 410-786-1620.)

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(g)); Use: Organizations contracted to offer Medicare Part C and Part D benefits are required to report data to us on a variety of measures. For the data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To meet this goal, we

have developed reporting standards and data validation specifications with respect to the Part C and Part D reporting requirements. These standards provide a review process for Medicare Advantage Organizations, Cost Plans, and Part D sponsors to use to conduct data validation checks on their reported Part C and Part D data.

The FDCF is revised for the 2017 and 2018 DV collection periods by changing the scoring of six standards from a binary scale to a five-point Likert-type scale. This change is expected to improve the precision of the data validation scores by increasing overall variation in total scores among the MAOs and PDPs. The revision is not expected to alter resource requirements, since the assessment by DV contractors in scoring standards will continue to be based on the percentage of records that meet the standards. Form Number: CMS-10305 (OMB control number: 0938-1115); Frequency: Yearly; Affected Public: Private sector - Business or other for-profits; Number of Respondents: 639; Total Annual Responses: 639; Total Annual Hours: 209,271. (For policy questions regarding this collection contact Terry Lied at 410-786-8973.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Evaluation of the CMS Quality Improvement Organizations: Reducing Healthcare-Acquired Conditions in Nursing Homes; Use: As mandated by Sections 1152-1154 of the Social Security Act, CMS directs the QIO program, one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries. In the 11th SOW, CMS restructured the QIO program to funded Quality Innovation Networks (QIN)-QIOs, Beneficiary and Family-Centered Care (BFCC) organizations, National Coordinating Centers (NCCs), Program Collaboration Centers (PCCs), and the Strategic Innovation Engine (SIE). In the current SOW, 14 QIN-QIOs coordinate the work of 53 QIOs nationwide including all 50 states and other U.S. territories.

CMS evaluates the quality and effectiveness of the QIO program as authorized in Part B of

Title XI of the Social Security Act. CMS created the Independent Evaluation Center (IEC) to provide CMS and its stakeholders with an independent and objective program evaluation of the 11th SOW. Evaluation activities will focus on analyzing how well the QIO program is achieving the three aims of better care, better health, and lower cost as well as the effectiveness of the new QIO program structure. One of the QIN-QIOs' tasks to achieve these three aims is to support participating nursing homes in their efforts to improve quality of care and health outcomes among residents. According to the 2013 CMS Nursing Home Data Compendium, more than 15,000 nursing homes participated in Medicare and Medicaid programs with more than 1.4 million beneficiaries resided in U.S. nursing homes. These residents and their families rely on nursing homes to provide reliable, safe, high quality care. However, cognitive and functional impairments, pain, incontinence, antipsychotic drug use, and healthcare associated conditions (HAC), such as pressure ulcers and falls, remain areas of concern.

This information collection is to provide data to assess QIN-QIOs efforts aimed at addressing these HACs in nursing homes. QIN-QIOs are responsible for recruiting nursing homes to participate in the program. We will conduct an annual survey of administrators of nursing homes participating in the QIN-QIO program (intervention group) and administrators at nursing homes that are not participating in the QIN-QIO program (comparison group). Our proposed survey assesses progress towards the goals of the QIN-QIO SOW, including activities and strategies to increase mobility among residents, reduce infections, reduce use of inappropriate antipsychotic medication among long-term stay residents.

We plan to conduct qualitative interviews with nursing home administrators. This interview will supplement the Nursing Home Survey and provide more in-depth contextual information about the QIN-QIO program implementation within at nursing homes, including: (i) their experience with, and

perceived success of QIN-QIO collaboratives; (ii) their satisfaction with the QIN-QIO Collaborative and QIO support; (iii) perceived value and impact of QIO program; and (iv) drivers and barriers to QIN-QIO involvement and success.

Information from QIO leadership and/or state/territory task leads will be collected by interviews and focus groups. Interviews with Nursing Home Task leaders at the QIN and QIO will be conducted in-person during site visits and/or over the phone. We will conduct focus groups with QIO-level Directors during the annual CMS Quality conference. The purpose of the interviews and focus groups is to examine: (i) QIO processes for recruiting nursing homes, peer coaches, and beneficiaries to participate in the program; (ii) strengths and challenges of QIN-QIO activities related to nursing homes; (iii) partnership and coordination with other QIN-QIO tasks; and (iv) overall lessons learned. We will also conduct qualitative interviews with nursing home peer coaches. Form Number: CMS–10622 (OMB control number: 0938–NEW); Frequency: Annually; Affected Public: Business or other for-profits and Not-for Profits institutions; Number of Respondents: 856; Total Annual Responses: 856; Total Annual Hours: 242. (For policy questions regarding this collection contact Robert Kambic at 410-786-1515)

Dated: June 27, 2016

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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